IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

ALPHARMA, Inc., a Delaware Corporation, Plaintiff, v. PENNFIELD OIL COMPANY, d/b/a Pennfield Animal Health, a Nebraska Corporation, Defendant.	8:03CV401 MEMORANDUM AND ORDER

This matter is before the court on the parties' cross-motions for summary judgment. Filing Nos. 171 & 174. This is an action for damages and injunctive relief for violations of the Lanham Act, 15 U.S.C. § 1125(a), the Nebraska Uniform Deceptive Trade Practices Act, NEB. REV. STAT. §§ 87-301 to 87-306, common-law unfair competition, and unjust enrichment in connection with defendant Pennfield's allegedly false advertising and promotion of one of its products. Specifically, Alpharma alleges that Pennfield falsely advertised that its animal-drug-feed-additive containing bacitracin methylene disalicyclate, marketed as Pennitracin MD 50-G, was approved by the Food and Drug Administration ("the FDA") for a number of uses for which it had not been approved. Filing No. 1, Complaint.

In their motions for summary judgment, both parties assert that undisputed evidence shows that each is entitled to judgment as a matter of law. Earlier in this litigation, this court granted Pennfield's motion to dismiss Alpharma's complaint. *See* Filing No. 49, Memorandum and Order at 4. The court found that the FDA was the proper forum in which to address the issues. *Id.* That finding was reversed by the Eighth Circuit Court of

Appeals. *Alpharma, Inc. v. Pennfield Oil Co.,* 411 F.3d at 941. The circuit court confirmed the viability of a Lanham Act false advertising claim. *Id.* at 940-41. It further found that "[t]he question of whether Pennfield's BMD [bacitracin methylene disalicyclate] has been approved as safe and effective is much different from the question of whether Pennfield's BMD should be approved as safe and effective, and it is only the latter that requires the FDA's scientific expertise." *Id.* at 939. The Eighth Circuit further stated: "A determination of whether Pennfield's product has received FDA approval for certain uses turns on the meaning of agency publications in the Federal Register and Code of Federal Regulations. Interpretation of such materials is well within the 'conventional experience of judges.'" *Id.* Accordingly, the only issue for resolution by this court is whether Pennfield's claims of FDA approval for certain uses were true at the time they were made. This court can determine, as a matter of law, whether Pennfield's Bacitracin MD product was FDA-approved.

I. BACKGROUND

A. Overview of Animal Drug Antibiotics Regulations

The FDA licenses the sale in interstate commerce of animal drugs by approving both the properties of the drug and its place and method of manufacture by granting a manufacturer's New Animal Drug Application ("NADA"), which remains on file with the FDA. See 21 U.S.C. § 360b(a); *American Cyanamid v. Fermenta Animal Health Co.,* 54 F.3d 177, 178 (3d Cir. 1995). During the early 1970s, a concern arose in the scientific community concerning the safety of widespread, long-term subtherapeutic use of

antibiotics in food-producing animals.[1] *United States v. An Article of Drug Consisting of 4,680 Pails, More or Less, Each Pail Containing 60 Packets,* 725 F.2d 976, 988 (5th Cir. 1984). This concern involved the possibility that the use of such drugs, over time, might favor the selection and development of antibiotic-resistant bacteria that might, under certain conditions, promote an increase in the prevalence of antibiotic-resistant bacteria in humans. *Id.*

In response to the concern, the FDA assembled an expert Antibiotic Task Force that studied the problem at some length and recommended to the FDA that extensive studies be undertaken to resolve the question of whether there was in fact any real danger of an increase in antibiotic-resistant, bacterially-induced disease in humans or animals due to the use of antibiotics in food-producing animals. *Id.* In 1972, the FDA proposed that all then-approved subtherapeutic or growth-promoting uses of antibiotics that were also approved for humans would be revoked unless certain data identified by the task force was submitted to the FDA. 37 Fed. Reg. 2444 (Feb. 1, 1972); *see also* 68 Fed. Reg. 47272, 47273 (Aug. 8, 2003) (summarizing the history of animal antibiotic drug regulations); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 284 (D. Mass. 1986) (noting that drugs and animal feeds that had already been approved would be allowed to remain on the market while this testing was performed). In 1974, the FDA published a proposed list of all of the drugs that had satisfied the criteria and were to be accorded interim marketing privileges. 39 Fed. Reg. 28382 (Aug. 6, 1974) (proposed

[1]Generally, subtherapeutic, long-term application of antibiotics in animals is usually intended to promote faster growth, improve feeding efficiency, and limit disease outbreaks, while therapeutic application of antibiotics is intended to treat disease and is administered in larger doses than for subtherapeutic use. *See United States v. An Article of Drug Consisting of 4,680 Pails, More or Less, Each Pail Containing 60 Packets,* 725 F.2d 976, 988 (5th Cir. 1984).

rules). After notice and opportunity for comment, the FDA published a final regulation, known as the interim marketing provision, at 21 C.F.R. § 135.109 (since renumbered 558.15)[2] that withdrew approval for those antimicrobial drugs not in compliance with the data submissions and listed the medicated premixes and drug combinations that had submitted the required data for agency review. 41 Fed. Reg. 8282 (Feb. 25, 1976); *see also* 68 Fed. Reg. at 47273. After a period of comment, a final rule listing the drugs covered by U.S.C. § 558.15 was issued by the FDA on February 25, 1976. 41 Fed. Reg. 8282 (Feb. 25, 1976).

In the discussion of the promulgation of the final rule, the FDA addressed a contention by Diamond Shamrock Corporation, a predecessor of Pennfield, that it had been erroneously omitted from the proposed list of approved sponsors of Type A medicated articles containing bacitracin methylene disalicyclate. 41 Fed. Reg. at 8287. Diamond Shamrock asserted that it had participated in cooperative studies to resolve the safety of bacitracin methylene disalicyclate, had submitted protocols in accordance with the requirements of the regulation, and had been authorized "by the holders of NADAs for bacitracin methylene disalicyclate to use the safety and effectiveness data in their files." *Id.* After reviewing the materials submitted by Diamond Shamrock, the FDA noted that Diamond Shamrock had "complied with the intent and critical elements of § 558.15" and "substantially complied with the regulation" and found that Diamond Shamrock should be added to the list of sponsors of antibacterial bacitracin methylene disalicyclate premixes in § 558.15 (g)(1). *Id.* Accordingly, the FDA determined that S.B. Penick and Diamond

[2]The FDA redesignated 21 U.S.C. § 135.109 as § 558.15 as part of a recodification of FDA regulations. 40 Fed. Reg. 13802 (March 27, 1975).

Shamrock were eligible for interim marketing of bacitracin methylene disalicyclate premix for chickens, turkey, cattle and swine based on compliance with the requirements of the section. *See* 41 Fed. Reg. at 8303 (final rule); 21 C.F.R. § 558.15 (1976). The regulation provided that the use levels and indications for use of the bacitracin methylene disalicyclate products were set out in 21 U.S.C. § 121.252 (later redesignated 21 U.S.C. § 558.76). *Id.*

Several years after the interim marketing regulation was issued, it became clear that the FDA's administrative records were incomplete, calling the approval status of certain products into question. 68 Fed. Reg. at 47273. Because the products listed in the interim marketing provision had been considered food additives before the Animal Drug Amendments of 1968, the agency's and the sponsor's ability to document pre-1968 approvals was limited. *Id.* at 47274. Accordingly, the FDA asked sponsors to certify the approval status of their products. *Id.* The agency then informed the involved parties that their certifications would be used as part of the administrative record of approval and stated "that it planned to codify the approvals as soon as possible, very likely in concert with the withdrawal of § 558.15." *Id.*

In the intervening years, the agency adopted a "new strategy and concept for assessing the safety of antimicrobial new animal drugs including subtherapeutic use of antimicrobials in animal feeds, with regard to the microbiologic effects on bacteria of human health concern." *Id.* In 1999, the FDA published a framework document, describing a possible approach by the FDA to regulate antimicrobials for use in food-producing animals. *Id., see also* 64 Fed. Reg. 70715 (Dec. 17, 1999). Draft guidance for the industry, subject to public comment, was proposed in 2002. 67 Fed. Reg. 58058 (Sept. 13, 2002). Accordingly, in 2003, the agency proposed to withdraw Section 558.15 because

"it long ago fulfilled its stated purpose of requiring sponsors to submit data regarding the subtherapeutic use of antibiotics on the market at the time of its publication." *Id.*

B. Uncontroverted Facts

The parties' statements of uncontroverted facts and the evidence submitted in connection with the motions establish the following uncontroverted facts. Plaintiff Alpharma, Inc. ("Alpharma") is a pharmaceutical company whose products include animal drugs for use as feed additives. Filing No. 1, Complaint at 2. Alpharma sells an animal drug product known as BMD®, a Type A Medicated Article containing bacitracin methylene disalicyclate. *Id.*; Filing No. 179, Plaintiff's Index of Evidence ("Evid."), Exhibit ("Ex.") B., Declaration of Sondra C. Flick ("Flick Decl.") at 1. It is undisputed that Alpharma has FDA approval to sell BMD® alone or in combination with other approved drugs for numerous uses. *See id.,* Ex. B, Flick Decl. at 2; Ex. A, Declaration of J. Douglas Behr ("Behr Decl."), Exs. A-1 to A-13 (attached thereto).[3] These approvals for use of bacitracin methylene disalicyclate in certain species and for specific indications supplement NADA 046-592. Flick Decl. at 3. On December 9, 1975, A.L. Laboratories, Inc. obtained the rights to NADA 046-592 for Bacitracin MD. *Id.* With reference to that new animal drug approval, Alpharma the successor in interest to S.B. Penick Company and to A.L. Laboratories, Inc. *Id.* Accordingly, Alpharma now owns NADA 046-592. *Id.*

Defendant Pennfield Oil Company, doing business as Pennfield Animal Health, is a Nebraska corporation with its principal place of business in Omaha, Nebraska. Filing No.

[3]*See* 46 Fed. Reg. 21,362-21,364 (April 10, 1981); 46 Fed. Reg. 21,748-21,749 (April 14, 1981); 46 Fed. Reg. 22,361 (April 17, 1981); 46 Fed. Reg. 22,754-22,755 (April 21, 1981); 47 Fed. Reg. 18,591 (April 30, 1982); 54 Fed. Reg. 7,189 (Feb. 17, 1989); 56 Fed. Reg. 21,076-21,077 (May 7, 1991), 63 Fed. Reg. 40,824 (July 31, 1998).

1, Complaint at 2. It also sells animal drugs for use as feed additives. *Id.* Pennfield's predecessors in interest, with respect to an approval to market bacitracin methylene disalicyclate, are Nopco Chemical Company, SDS Biotech, Diamond Shamrock Chemical Company ("Diamond Shamrock"), Fermenta Animal Health ("Fermenta"), and Boehringer Ingelheim Vetmedica, Inc. ("BIVI"). Pennfield purchased the right to market a bacitracin methylene disalicyclate product, NADA141-137, from BIVI in 2002. Filing No. 153, Defendant's Index of Evid., Ex. 2, Declaration of Gregory Bergt ("Bergt Decl.") at 2.

From November 2002 until November 2004, Pennfield advertised and sold a Type A Medicated Article containing bacitracin methylene disalicyclate under the name Pennitracin MD 5·G ("Pennitracin MD"). *Id.,* Bergt Decl. at 4. On the Pennitracin MD label and product information sheet is the statement "NADA 141-137, FDA Approved." *Id.,* Bergt Decl. at attached Ex. 4; Filing No. 1, Complaint at 5-7, and attached Ex. 4. The Pennitracin label states that the product is generally indicated for: increased rate of weight gain and feed efficiency and control of dysentery in growing/finishing swine; control of enteritis in pregnant sows; reduction in the number of liver condemnations due to abscesses in feedlot beef cattle; increased rate of weight gain and feed efficiency and prevention and control of necrotic enteritis in broiler chickens; increased egg production and improved feed efficiency in laying hens; increased rate of weight gain and improved feed efficiency and as an aid in control of transmissible enteritis in growing turkeys; increased rate of weight gain and feed efficiency in pheasants; and increased rate of weight gain and feed efficiency and prevention of ulcerative enteritis in quail. *See id.* Pennfield stopped marketing Pennitracin after November 2004 for reasons unrelated to this litigation, but due to problems with raw material supply. *Id.*, Ex. 2, Bergt Decl. at 4.

Documentary evidence submitted to the court in support of and in opposition to the motions establishes that, in 1995, Dr. Donald Gable, D.V.M., then employed by Pennfield's predecessor, Fermenta, contacted the FDA's Center for Veterinary Medicine ("FDA-CVM") to determine the extent of Fermenta's marketing rights for bacitracin methylene disalicyclate.[4] Filing No. 173, Defendant's Index of Evid., Ex. 1.B.35 (Gable letter dated May 5, 1995). On June 22, 1995, Dr. Gable sent another letter to the FDA-CVM seeking clarification of the FDA's position, along with documentation that Pennfield's predecessor, Diamond Shamrock, had been approved to market bacitracin methylene disalicyclate in 1976. *Id.,* Ex. 1.B.36 (Gable letter dated June 22, 1995). Dr. Gable later met with Dr. Andrew Beaulieu and Dr. Dianne McRae of the FDA-CVM on May 31, 1996, to discuss the issue. *Id.,* Exs. 1.B.40, 1.B.41, & 1.B42. Correspondence from Dr. Beaulieu to Dr. Gable after the meeting indicated that Fermenta's bacitracin methylene disalicyclate Type A medicated article had been granted interim marketing rights under 21 U.S.C. § 558.15. *Id.*, Ex. 1.B.44 (letter dated June 13, 1996). Dr. Beaulieu stated:

> Your BMD Type A medicated article is listed under 558.15 and is, therefore, eligible for the interim privileges provided by the regulation. Based on a review of available files, we were not able to establish that your product has ever been approved either by a form 6 or otherwise. However, as previously noted, this does not prevent you from marketing your product at this time under the provisions of [21 U.S.C. § 558.15].

Id. He further noted that Fermenta was entitled to continue marketing its Bacitracin MD product until the FDA revoked the interim marketing rights authorized by § 558.15, stating that the FDA-CVM did not plan to begin the process of revoking § 558.15 interim marketing

[4]Prior to his employment at Fermenta, Dr. Gable was the Director of the FDA-CVM's Division of Therapeutic Drugs for Food Animals. Filing No. 173, Defendant's Index of Evid., Ex. 1.B.3, Declaration of Donald Gable, D.V.M. ("Gable Decl.") at 2. He was previously a Staff Officer in the Office of the Center Director, where he was involved in the Drug Efficacy Study Implementation ("DESI") review process. *Id.*

privileges in the immediate future and that because "the process involv[ed] notice-and-comment rulemaking, it [would] take a considerable period of time to conclude such an action once it [was] initiated." *Id.*

In 1998, after Fermenta was acquired by BIVI, Dr. Gable, then employed by BIVI, wrote to the FDA-CVM to clarify the species and uses for which BIVI could market its bacitracin methylene disalicyclate product under the interim marketing rights. *Id.,* Ex. 1.B.47 (letter dated July 16, 1998). Dr. Stephen Sundlof, the director of the FDA's Center for Veterinary Medicine, responded that the FDA's records of approvals were incomplete and asked Dr. Gable to certify that the bacitracin methylene disalicyclate product approval that BIVI acquired from Fermenta had been approved before § 558.15 had been promulgated in 1976. *Id.,* Ex.1.B.49.[5] Dr. Gable responded to the request and presented evidence that BIVI's bacitracin methylene disalicyclate product had been properly included within § 558.15. *Id.*, Ex.1.B.50 (letter dated September 18, 1998) and Ex.1.B.51 (letter dated November 17, 1998). The documentation submitted by Dr. Gable included a 1969 label for BIVI's predecessor's bacitracin methylene disalicyclate product, Noptracin MD 50, and correspondence that shows that Diamond Shamrock was one of several manufacturers who sponsored studies required by § 558.15 as part of a sub-group of the Animal Health Institute ("AHI"). *Id.* Dr. Gable also provided results of investigations, protocols and reports of studies by the AHI subgroup and Diamond Shamrock that were

[5]As of 2003, Section 558.15(g)(1) still listed Fermenta as the sponsor for Pennfield's bacitracin methylene disalicyclate product, even though the FDA has been advised of the transfers of ownership from Fermenta to BIVI and from BIVI to Pennfield. *See* Ex. 1.D.3; 68 Fed. Reg. 47332, 47333 (Aug. 8, 2003). Federal regulations were amended to reflect a change in product name from Fortracin to Pennitracin in 68 Fed. Reg. 47332 on October 3, 2003. *See* 68 Fed. Reg. 57911. Also, BIVI had been substituted for Fermenta as sponsor for bacitracin methylene disalicyclate in § 558.15 in 1999. *See* 64 Fed. Reg. 37672.

designed to satisfy the requirements of § 558.15. *Id.* On November 27, 1998, the FDA sent Dr. Gable a letter assigning NADA 141-137 to BIVI's Bacitracin MD product. *Id.,* Ex. 1.B.53. The FDA confirmed receipt of Dr. Gable's certification and indicated it would be included in the FDA's administrative record of the approval of NADA 141-137.

Two versions of the label that BIVI proposed to use for its bacitracin methylene disalicyclate product, then named "Noptracin MD 50," were faxed to Dr. Diane McRae at the FDA-CVM on December 9, 1998. *Id.,* Ex. 1.B.54. Both labels listed each specific indication and condition for use for which BIVI proposed to market its bacitracin methylene disalicyclate product, which included all single use claims available under § 558.76 at that time. *Id.,* Ex. 1.D.6; 21 C.F.R. § 558.76(1998).[6] The indications for use and species listed on the proposed Noptracin MD 50 labels that Dr. Gable faxed to the FDA-CVM on December 9, 1998, are the same indications for use at issue in this litigation. Copies of both of the Noptracin MD 50 labels are maintained in the official administrative file maintained by FDA-CVM for NADA 141-137. *Id.*, Ex. 1.C.8; Ex. 3.

In a letter dated December 17, 1998, Dr. Sundlof confirmed the FDA's approval of NADA 141-137 for all uses listed on the Noptracin MD labels:

> In accordance with my letter, your certification will be used along with information in our files as the administrative record of an approval for NADA 141-137, which provides for a Type A Medicated Article, Noptracin® MD-50 (bacitracin methylene disalicyclate) for use for the indications and under the

[6]Section 58.15 provided that bacitracin methylene disalicyclate was approved for the following conditions and species: for increased rate of weight gain and improved feed efficiency in chickens, turkeys and pheasants; for increased egg months of production ans improved feed efficiency for egg production in chickens; for increased rate of weight gain and treatment of bacterial enteritis in swine; as an aid in the prevention of necrotic enteritis in broiler chickens; as an aid in the control of transmissible enteritis in growing turkeys; for the prevention of medicated enteritis in growing quail; for control of dysentery in swine; for control of enteritis and scours in pregnant sows; and for reduction in the number of liver condemnations due to abscesses in feedlot beef cattle. 21 C.F.R. § 558.76 (1998).

> conditions of use specified in the labeling attached to your letter. The agency will begin the work of codifying the approval via publication in the Federal Register. . . . In the meantime, you may rely on this letter to verify the approved status of NADA 141-137.

Id., Ex. 1.B.55.

On May 1, 2002, representatives of FDA-CVM, Pennfield, and BIVI met to discuss the sale and transfer of NADA 141-137 f rom BIVI to Pennfield. In a memorandum of that conference prepared after the meeting by Dr. Dianne McRae, the FDA-CVM confirmed that the agency had no problem with the transfer "other than that the current regulations would have to reflect the transfer, delete Fermenta Animal Health as the current sponsor and codify the NADA in an approved section of the 21 C.F.R. § 558 (*i.e.,* 558.76) [that] would complete the certification approval status of [NADA 141-137]." *Id.,* Ex. 1.B.63. BIVI's notes of the meeting are consistent with those of the FDA and indicate that the FDA-CVM "raised no issues during the meeting for this NADA that would adversely impact that NADA or its transfer to [Pennfield]." *Id.,* Ex. 1.B.64. In the asset purchase agreement for NADA 141-137, BIVI represented to Pennfield that NADA 141-137 had been approved by the FDA for all uses and indications appearing on the Noptracin labels BIVI had furnished to the FDA. *Id.,* Ex. 1.B.73 at § 3.7.

On August 19, 2002, Pennfield advised the FDA-CVM of the transfer of sponsorship and ownership of NADA 141-137 from BIVI to Pennfield. *Id.,* Ex. 2, Bergt Decl. at 3. A memo prepared on October 1, 2002, by Gregory Gates, Consumer Safety Director at the FDA states:

> Pennefield [sic] Oil Company has informed CVM of their acceptance of ownership of this file . . . from [BIVI]. This product is approved but has not been codified in the C.F.R. It has been decided that we will codify the approval of NADA 141-137 at the time we publish the notice of withdrawal

> of 21 C.F.R. § 558.15. At that time we will codify this approval at 21 C.F.R. § 558.76 for Bacitracin Methylene Disalicyclate.

Id., Ex. 1.C.4. The FDA-CVM sent a letter to Pennfield acknowledging receipt of the transfer documents and stating: "We will codify the approval of NADA 141-137 at the time we publish the notice of withdrawal of 21 C.F.R. § 558.15. At that time we will codify this approval at 21 C.F.R. § 558.76 for Bacitracin Methylene Disalicyclate." *Id*., Ex. 2, Bergt Decl. at attached Ex. 3 (FDA letter dated October 3, 2002). To date, the FDA has not withdrawn 21 C.F.R. § 558.15 with respect to Pennfield's bacitracin methylene disalicyclate product.

Pennfield later submitted updated information to the FDA, including three copies of its proposed Pennitracin MD labeling. *Id.,* Ex. 1.C.5 (Bergt letter dated Nov. 14, 2002). The Pennitracin MD labels that Pennfield submitted to the FDA in November 2002 listed species and indications for use identical to the species and indications for use listed on the Noptracin MD labels submitted by BIVI to the FDA in 1998 and in 2002. *Id.,* Ex. 2, Bergt Decl. at 4. The actual production label used by Pennfield to market Pennitracin MD also listed species and indications for use identical to the Noptracin MD labels. *Id.*

The record also shows that in May 2003, prior to filing suit in this court against Pennfield, Alpharma filed an action against the Commissioner of the Food and Drug Administration in the United States District Court for the District of Maryland seeking a declaration that the FDA had unlawfully granted Pennfield approval to sell bacitracin methylene disalicyclate or had "unlawfully facilitate[d] Pennfield's false representation of FDA approval for BMD." *See Pennfield Oil Company v. American Feed Indus. Ins. Co. Risk Retention Group, Inc.,* No. 8:05-CV-315, Filing No. 45, Defendant's Index of Evid., Ex.

L. at 8, 14 (Alpharma Complaint) (D. Neb. Aug. 30, 2006); *Alpharma, Inc. v. McClellan,* No. 03-CV-1406, Filing No. 1, Complaint (M. D. Md. May 13, 2003) (hereinafter, "the Maryland action"). The Maryland action was later dismissed pursuant to a stipulated order, wherein the FDA agreed that its records did not show that Pennfield's predecessors' bacitracin methylene disalicyclate product had been approved for multiple uses, but also opened the issue for comment and rulemaking. *See Pennfield Oil Company v. American Feed Indus.,* No. 8:05-CV-315, Filing No. 45, Ex. M, Stipulation and Order at 3-4; *Alpharma, Inc. v. McClellan,* No. 03CV1406, Filing No. 15, Order (D. Md. August 15, 2003); *see also Alpharma, Inc. v. Pennfield,* 411 F.3d at 939.

Subsequently, the FDA published two notices in the Federal Register. *See* 68 Fed. Reg. 47272 (Aug. 8, 2003); 68 Fed. Reg. 47332 (Aug. 8, 2003). One contained a proposed rule change: to remove obsolete and redundant regulations, primarily focusing on the removal of § 558.15. *See* 68 Fed. Reg. 47272 (Aug. 8, 2003). The FDA also issued a Notice of Opportunity for Hearing ("NOOH") with respect to the withdrawal of its approval of NADA 141-137 with respect to certain species and indications for use. *See* 68 Fed. Reg. 47332, 47339 (Aug. 8, 2003).

In the NOOH, the FDA states that "NADA 141-137, FORTRACIN MD 50 (BMD) Type A medicated article used to make Type B and Type C medicated feeds" is covered by the DESI findings of effectiveness for BMD in animal feed and lists Pennfield Oil Co. as its sponsor. *Id.* at 47333 (stating "[i]n 1970, FDA announced its DESI [Drug Effectiveness Study Implementation] findings of effectiveness for feed use of BMD (35 Fed. Reg. 11531, July 17, 1970, as corrected by 35 Fed. Reg. 15408, October 2, 1970)"). The FDA explains that the notice of hearing was necessary because of "several potential sources of

confusion regarding NADA 141-137 and the interim marketing provision for bacitracin methylene disalicyclate in § 558.15(g)(1)." *Id*. The FDA first points out that the sponsors listed in the regulation for BMD—A. L. Laboratories, Inc., and Fermenta Animal Health Co.—are outdated. *Id.* Also, the FDA notes that a source of confusion is that the regulation cross-references another section of the regulations for the indications for use for which the interim marketing is permitted, and acknowledges that the agency had failed to update or amend the regulation to reflect the approval of supplemental applications. *Id.* at 47334. Additionally the FDA states that "[t]he confusion caused by the reference in § 558.15(g)(1) to the use levels and indications for use in § 558.76 is illustrated by, and perhaps exacerbated by, the administrative record for NADA 141-137." *Id.* The FDA explains that to help resolve questions presented by the lack of adequate records of its approval process, BIVI certified in 1998 that the product had been approved prior to 1968 and had provided supporting information, including information about the approved indications. *Id.* The FDA explains:

> One piece of information, included with the September letter, is a product label dated February 1969. BIVI stated that this label is consistent with § 558.15. This was probably intended to mean the interim marketing table in § 558.15 as it was originally issued in 1976 since the label's indications are generally consistent with, albeit somewhat narrower than, BMD's indications listed in the table at the time. Given this consistency and given that the date of the label is just a few months before the effective date of the transitional approval provision, the label provides good evidence that the product was subject to transitional approval and the indications for which it was transitionally approved.

Id. The FDA concludes that "[i]t is unclear whether BIVI meant the indications in § 558.76 in 1976 or 1998." It confirmed, however, that BIVI had been granted approval, and that "the agency planned to codify this approval as soon as possible given resource constraints

and public health priorities," but that it was unaware of any approved indications beyond those listed in the original § 558.76 from 1976 for Pennfield Oil Co.'s product." *Id.* Accordingly, it requested that additional information on the other approved indications be provided to FDA during this administrative process. *Id.*

The record shows that Pennfield responded to the NOOH and submitted argument and evidence to the FDA-CVM. *See, e.g., Pennfield Oil Company v. American Feed Indus.,* No. 8:05-CV-315, Filing No. 45, Exs. O & R (Pennfield's letter briefs to FDA). The FDA later addressed the issue of withdrawal of § 558.15 (the subject of the proposed rule change set out in 68 Fed. Reg. 47472) in a 2006 regulation. 71 Fed. Reg. 16219-01 (March 31, 2006). The FDA states that it received comments on its proposed rule change from Pennfield Oil Co. and that "Pennfield owns a bacitracin methylene disalicyclate (BMD) Type A medicated article, NADA 141-137, that is listed in the table in § 558.15(g)(1)." *Id.* (noting also that "[t]his listing is under Fermenta Animal Health Co., which is a predecessor in interest to Pennfield"). The FDA notes:

> [Pennfield's] comment objected to removal of § 558.15 until the issues in the NOOH [68 Fed. Reg. 47332] are addressed. It argued that the BMD listing in § 558.15 provides evidence of Pennfield's approval and that removal of that section, without updating the BMD listing in part 558 subpart B, would result in a lack of recognition in the regulations of the approval that Pennfield currently has.

Id. Accordingly, "FDA agrees that it should, at this time, maintain the listing for Pennfield's BMD Type A medicated article in § 558.15 . . . until, as part of the DESI program, either their approvals are withdrawn or part 558 subpart B has been amended to reflect their approvals. *Id.* The regulation was amended accordingly. 21 C.F.R. 558.15 (2006). No

further action has been taken with respect to the NOOH that proposed withdrawing NADA 141-137 with respect to certain species and indications.

II. DISCUSSION

A. Law

On a motion for summary judgment, the question before the court is whether the record, when viewed in the light most favorable to the nonmoving party, shows that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005). Where unresolved issues are primarily legal rather than factual, summary judgment is particularly appropriate. *Mansker v. TMG Life Ins. Co.*, 54 F.3d 1322, 1326 (8th Cir. 1995). The FDA's rules are governed by plain language and reasonable interpretation and they are binding as a matter of law. *See Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973). Also, the contents of the Federal Register are judicially noticed. *See* 44 U.S.C. § 1507.

Under the Lanham Act, "[a]ny person who, on or in connection with any goods or services . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act." 15 U.S.C. § 1125(a)(1)(B). "In general, the statute is broadly construed as 'making certain types of unfair competition federal statutory torts.'" *American Ass'n of Orthodontists v. Yellow Book USA, Inc.,* 434 F.3d 1100, 1102 (8th Cir. 2006) (*quoting Home Builders Ass'n v. L & L Exhibition Mgmt., Inc.,* 226 F.3d 944, 947 (8th Cir. 2000)).

The Lanham Act was intended, in part, to protect persons engaged in commerce against false advertising and unfair competition. *See Two Pesos, Inc. v. Taco Cabana, Inc.,* 505 U.S. 763, 767-68 (1992) (*quoting* 15 U.S.C. § 1127). In particular, the Act prohibits commercial advertising or promotion that misrepresents the nature, characteristics, qualities, or geographic origin of the advertiser's or another person's goods, services, or commercial activities. *United Indus. Corp. v. Clorox Co.,* 140 F.3d 1175, 1179-80 (8th Cir. 1998). In order to be actionable under the Act, the false statement must be made in commercial advertising or promotion. *See Aviation Charter, Inc. v. Aviation Research Group/US,* 416 F.3d 864, 871 (8th Cir. 2005). For a statement to constitute commercial advertising or promotion, it must be made, *inter alia*, by a defendant who is in commercial competition with the plaintiff. *Id.*

To establish a claim for false or deceptive advertising under Lanham Act, a plaintiff must prove: (1) a false statement of fact by a defendant in commercial advertisement about its own or another's product; (2) the statement actually deceived or has a tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence a purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as result of the false statement, either by direct diversion of sales from itself to the defendant or by loss of goodwill associated with its products. *United Indus. Corp. v. Clorox Co.,* 140 F.3d at 1180; 15 U.S.C.A. § 1125(a).

The false statement necessary to establish a Lanham Act violation generally falls into one of two categories: (1) commercial claims that are literally false as a factual matter; and (2) claims that may be literally true or ambiguous but which implicitly convey a false

impression, are misleading in context, or likely to deceive consumers. *United Indus. Co. v. Clorox Co.,* 140 F.3d at 1180. If a plaintiff proves that a challenged claim is literally false, a court may grant relief without considering whether the buying public was actually misled; actual consumer confusion need not be proved. *Id.*; *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.,* 938 F.2d 1544, 1549 (2d Cir.1991) (where an advertisement is shown to be literally false, court may enjoin it without reference to its impact on consumers). In assessing whether an advertisement is literally false, a court must analyze the message conveyed within its full context. *United Indus. Corp.,* 140 F.3d at 1181-82 (holding that statements that are literally true or ambiguous but which nevertheless have a tendency to mislead or deceive the consumer are actionable under the Act, absent a willful violation or an intent to deceive, only with evidence of consumer impact). A party seeking relief for implicitly false or misleading claims under the Lanham Act bears the ultimate burden of proving actual deception by using reliable consumer or market research. *Id.* at 1182. State law claims for false advertising are generally coextensive with federal claims. *DaimlerChrysler AG v. Bloom,* 315 F.3d 932, 935 n. 2 (8th Cir. 2003) (involving Minnesota law).

III. ANALYSIS

The court finds that the undisputed evidence submitted to the court shows that the defendant is entitled to judgment as a matter of law. The issue for resolution by the court is whether Pennfield's statements were literally false, or if true, whether they implicitly conveyed a false impression, were misleading in context, or were likely to deceive consumers. By the FDA's own admission, there exists considerable confusion with respect to the historical facts of Pennfield's or its predecessors' approval to market a Type A

Medicated Article containing bacitracin methylene disalicyclate and the approved species and conditions for which it was approved. In the NOOH that it published in response to Alpharma's action challenging its regulations, the FDA intimated that its prior approval may have been in error. Whether or not the approval was erroneous or improvident is not the issue. The regulations and commentary set out in the Federal Register after it issued the NOOH show that the FDA, properly or not, had approved the Pennfield product by the time Pennfield stated it had such approval to market its product. The fact that the FDA addressed the issue through the notice and rulemaking procedure indicates that the FDA perceived that Pennfield had an expectation deserving of due process protection. Importantly, Pennfield was never told by the FDA to stop marketing Pennitracin.

Even if approval were not granted earlier, Pennfield was entitled to rely on the FDA's representations to BIVI in 1995 and 1998 that Pennfield's bacitracin methylene disalicyclate feed additive was approved. In its most recent pronouncement, the regulation codified in 2006, the FDA lists Pennfield as a sponsor of an approved bacitracin methylene disalicyclate animal feed additive product. The court finds that Alpharma has failed to meet its burden of showing that the statements at issue were literally false. Nor has it shown that the true statements were implicitly misleading. The court finds that the evidence establishes that Pennfield is entitled to summary judgment in its favor on the plaintiff's Lanham Act claim. Similarly, Alpharma cannot recover under the Nebraska Deceptive Trade Practices Act, or establish a claim for common-law unfair competition or unjust enrichment. Accordingly,

IT IS ORDERED:

1. Plaintiff's motion for summary judgment (Filing No. 174) is denied;

2. Defendant's motion for summary judgment (Filing No. 171) is granted;

3. A Judgment will be entered in conformity with this Memorandum and Order.

DATED this 5th day of May, 2008.

BY THE COURT:

s/ Joseph F. Bataillon
Chief United States District Judge